



**U.S. Department of Justice**

*United States Attorney  
District of New Jersey*

970 Broad Street, 7<sup>th</sup> floor  
Newark, New Jersey 07102

973-645-2700

JTE/PL AGR  
2011R00148

August 29, 2014

Brien T. O'Connor, Esq.  
Joshua S. Levy, Esq.  
Ropes & Gray LLP Prudential Tower  
800 Boylston Street  
Boston, Massachusetts 02199

Re: Plea Agreement with OtisMed Corporation

14-CR-688(CCC)

Dear Messrs. O'Connor and Levy:

This letter sets forth the plea agreement between the United States Attorney for the District of New Jersey and the United States Department of Justice, by and through the Consumer Protection Branch (collectively, the "United States") and your client, OtisMed Corporation ("OtisMed"), a subsidiary of Stryker Corporation ("Stryker").

Charge

Conditioned on the understandings specified below, the United States will accept a guilty plea from OtisMed to a one-count felony Information, which charges OtisMed with the introduction into interstate commerce, with the intent to defraud and mislead, of medical devices that were adulterated (pursuant to 21 U.S.C. § 351(f)(1)(B)) in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(2). If OtisMed enters a guilty plea and a judgment of conviction is entered that is consistent with the terms of the agreed disposition included in this plea agreement under Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, and if OtisMed otherwise fully complies with all of the terms of this agreement, the United States will not initiate any further criminal charges against OtisMed with respect to its sales, marketing and distribution of the OtisKnee Orthopedic Cutting Guides (hereinafter "OtisKnee") medical device between

May 2006 and November 2009. However, in the event that a guilty plea in this matter is not entered for any reason or the judgment of conviction entered as a result of this guilty plea does not remain in full force and effect, OtisMed agrees that any dismissed charges and any other charges that were not time-barred by the applicable statute of limitations on the date this agreement is signed by OtisMed may be commenced against OtisMed, notwithstanding the expiration of the limitations period after OtisMed signs the agreement.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of OtisMed, in connection with the conduct encompassed by this plea agreement or known to the United States.

### Sentencing

The violation of 21 U.S.C. §§ 331(a) and 333(a)(2) to which OtisMed agrees to plead guilty carries a statutory maximum term of probation of 5 years, and a statutory maximum fine equal to the greatest of: (1) \$500,000; (2) twice the gross amount of any pecuniary gain derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. See 18 U.S.C. §§ 3561(c)(1), 3571(c)(3), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

Further, in addition to imposing any other penalty on OtisMed, the sentencing judge: (1) will order OtisMed to pay an assessment of \$400 pursuant to 18 U.S.C. § 3013, which assessment must be paid by the date of sentencing; and (2) may order OtisMed to pay restitution pursuant to 18 U.S.C. § 3563.

The parties agree that the fine agreed upon by the parties is consistent with the United States Sentencing Guidelines ("U.S.S.G.") and takes into account OtisMed's conduct under 18 U.S.C. §§ 3553 and 3572, as follows:

- (1) The parties agree that the base fine is \$34,400,000, in that such amount was the reasonably estimated pecuniary gain to OtisMed from the offense, see U.S.S.G. §§ 8C2.3, 8C2.4(a);
- (2) Pursuant to U.S.S.G. § 8C2.5, the culpability score is five (5), which is determined as follows:

- (i) Base culpability score of five (5) pursuant to U.S.S.G. § 8C2.5(a);
- (ii) Add two (2) points pursuant to U.S.S.G. § 8C2.5(b)(4) because the organization had 50 or more employees, and an individual within substantial authority personnel of the organization participated in the offense;

and

- (iii) Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) for OtisMed's full cooperation in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct after its acquisition by Stryker.
- (3) Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of five (5) is 1.0 to 2.0; and
  - (4) Therefore, the advisory Guidelines Fine Range is \$34,400,000 to \$68,800,000.

#### Agreed Disposition

The United States and OtisMed agree that, pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the appropriate disposition of the case is as follows, and will result in the imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, and taking into account that \$40,000,000 plus interest will be paid to resolve the civil investigation arising out of the same course of conduct, pursuant to an agreement with the U.S. Attorney's Office for the District of New Jersey and the United States Department of Justice's Civil Division, Fraud Section, attached hereto as Exhibit 1, to settle related civil claims:

- (1) OtisMed shall pay a criminal fine in the amount of \$34,400,000 within seven (7) days after sentencing;
- (2) OtisMed shall be subject to pay criminal forfeiture in the amount of \$5,160,000 within seven (7) days after sentencing;

- (3) OtisMed shall pay a special assessment of \$400, which shall be paid to the Clerk of Court on or before the date of sentencing;
- (4) The United States agrees that it will not seek a separate restitution order as to OtisMed as part of the resolution of the charge in the Information. The United States and OtisMed agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweigh the need to provide restitution to non-governmental victims, if any, in this case; and
- (5) The United States further agrees that it will not seek a term of probation in light of: (i) the remedial measures undertaken by OtisMed after its acquisition by Stryker; (ii) the enhanced corporate rehabilitative compliance measures and certifications agreed to by Stryker as attached hereto as Exhibit 2; and (iii) OtisMed's agreement with the Office of Inspector General, U.S. Department of Health and Human Services to be excluded from participating in all Federal healthcare programs for a period of 20 years, see Exhibit 1.

Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the United States and OtisMed agree that no other sentence or fine is appropriate, beside those set forth above. If the Court accepts this plea agreement, OtisMed must be sentenced accordingly. If the Court rejects any aspect of this plea agreement or fails to impose a sentence consistent herewith, this agreement shall be null and void at the option of either the United States or OtisMed, except that OtisMed expressly waives, and agrees that it will not interpose, any defense to any charges brought against OtisMed which OtisMed might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act. If OtisMed fails to pay any amounts within the time frames specified in this plea agreement, this agreement shall be null and void at the sole option of the United States. See 18 U.S.C. § 3614.

#### Rights of the Parties Regarding Sentencing

Except as otherwise provided in this agreement, all parties to this agreement reserve their rights to correct any

misstatements relating to the sentencing proceedings, and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, the parties may inform the sentencing judge and the United States Probation Office of: (1) this agreement; and (2) the full nature and extent of OtisMed's activities and relevant conduct with respect to this case.

Agreement Not to Prosecute

Except as provided herein, the United States agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges or forfeiture action against OtisMed, its present and former parent companies, affiliates, divisions, and subsidiaries, or their predecessors, successors, and assigns, for conduct which (1) falls within the scope of the investigation in the District of New Jersey relating to the OtisKnee, or (2) was known to the United States Attorney's Office for the District of New Jersey or the Consumer Protection Branch of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the OtisKnee in the United States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the District of New Jersey, the Consumer Protection Branch, Civil Division, of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions in this paragraph are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of OtisMed, its subsidiaries, affiliates, or parent that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of OtisMed's products to foreign customers, which investigations are specifically excluded from the release in this paragraph. Attached as Exhibit 3 to this agreement is a copy of the letter to United States Attorney Paul J. Fishman from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

OtisMed understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice, except as specified in this agreement. Further, OtisMed understands that the United States takes no position as to the proper tax treatment of any of the payments made by OtisMed pursuant to this plea agreement, any



civil settlement agreement, or any agreement with the Department of Health and Human Services.

Waiver of Appeal and Post-Sentencing Rights

OtisMed knowingly and voluntarily waives the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2255, which challenges the conviction or sentence imposed by the Court if the plea is accepted and the sentence is imposed in accordance with the terms of this agreement.

The United States will not file any appeal, motion or writ which challenges the conviction or sentence imposed by the Court if that sentence is imposed in accordance with the terms of this agreement. Furthermore, if the Court accepts the terms of this plea agreement, both parties waive the right to file an appeal, collateral attack, writ, or motion claiming that the Court erred in doing so.

Both parties reserve the right to oppose or move to dismiss any appeal, collateral attack, writ, or motion barred by the preceding paragraphs.

Forfeiture

OtisMed agrees that as part of its acceptance of responsibility, OtisMed will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c). OtisMed admits that the value of the quantities of the OtisKnee that were distributed in violation of 21 U.S.C. § 331 totaled approximately \$5,160,000 in United States currency.

OtisMed acknowledges and agrees that the quantities of the OtisKnee that were distributed in violation of 21 U.S.C. § 331 cannot be located upon the exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property that cannot be divided without difficulty. Accordingly, OtisMed agrees that the United States is entitled to forfeit as "substitute assets" any other assets of OtisMed up to the value of the now-missing directly forfeitable assets.

OtisMed agrees that, within seven (7) days after sentencing, it shall remit the amount of \$5,160,000 in United States currency to the United States Marshals Service. Payment

shall be made by certified or bank check payable to the United States Marshals Service. Within seven (7) days after sentencing, OtisMed shall cause said check to be hand-delivered to Assistant United States Attorney Jacob T. Elberg, United States Attorney's Office, District of New Jersey, 970 Broad Street, Newark, New Jersey 07102. OtisMed and the United States agree that this payment shall satisfy any and all forfeiture obligations that OtisMed may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of OtisMed's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon OtisMed, nor shall the forfeiture be used to offset OtisMed's tax liability or any other debt owed to the United States.

OtisMed agrees to consent to the entry of an order of forfeiture for \$5,160,000 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. OtisMed acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the Court to advise it of this, pursuant to Federal Rule of Criminal Procedure 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this agreement, OtisMed hereby waives any and all claims arising from or relating to the forfeiture set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment to the United States Constitution, or any other provision of state or federal law. The United States District Court for the District of New Jersey shall retain jurisdiction to enforce the provisions of this section.

#### Notification to Healthcare Providers

Within ninety (90) days after OtisMed is sentenced pursuant to this agreement, OtisMed will provide notice of the Information and this agreement to all customers to whom OtisMed distributed the OtisKnee. Specifically, OtisMed shall send, by first class mail, postage prepaid, a notice containing the

language set forth below to all Health Care Providers to whom OtisMed distributed the OtisKnee:

"As you may be aware, in December 2009, Stryker Corporation acquired OtisMed Corporation. In September 2010, Stryker received a Civil Investigative Demand from the U.S. Department of Justice relating to OtisMed. In September 2014, OtisMed agreed to enter into a global resolution, including a criminal plea agreement and a civil settlement with the United States in connection with OtisMed's marketing and distribution of OtisKnee Orthopedic Cutting Guides ("OtisKnee") between 2006-2009 - before Stryker acquired OtisMed. This letter provides you with additional information about the settlement.

The resolution described in this letter **does not pertain** to the Stryker product known as the ShapeMatch Cutting Guide, a different device marketed and distributed by Stryker that received 510(k) clearance in May 2011. This settlement pertains to a device known as the OtisKnee, which was marketed and distributed by OtisMed from 2006 through September 2009, before OtisMed was acquired by Stryker.

In general terms, OtisMed has admitted that OtisMed illegally distributed the OtisKnee without the approval or clearance of the Food and Drug Administration ("FDA") in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). In the United States, the FDA regulates the sale of and monitors the safety of medical device products. Before certain medical devices can be legally sold in the United States, the manufacturer must request permission from the FDA, after presenting evidence that the device is reasonably safe and effective for the particular use for which it is intended. Because OtisMed did not obtain approval or clearance from the FDA prior to distributing the OtisKnee, the OtisKnee is considered to have been an "adulterated" medical device under the FDCA. OtisMed pleaded guilty to introduction of an adulterated medical device into interstate commerce with the intent to defraud and mislead in the United States District Court for the District of New Jersey. OtisMed has agreed to pay a fine and forfeiture of \$39.56 million. In addition, OtisMed has entered into a civil settlement agreement to settle allegations that OtisMed violated the False Claims Act. Pursuant



to this civil settlement agreement, OtisMed has agreed to pay an additional \$40 million plus interest to the Federal Government. More information about this settlement, including OtisMed's plea agreement, the Information, and the civil settlement agreement, may be found at [OtisMed shall include a link to the USAO website in the letter].

As part of the federal settlement, Stryker, which acquired OtisMed after the conduct that is the basis for this criminal charge, committed to maintaining its Compliance Program. Under this agreement, which is available at [OtisMed shall include a link to the USAO website in the letter], Stryker agreed to continue to undertake certain actions designed to promote compliance with Federal health care program and FDCA requirements and make periodic certifications to the Department of Justice. Stryker also agreed to provide this notice to Health Care Providers.

You may report any improper conduct associated with device marketing to the FDA's Center for Devices and Radiological Health (CDRH) Allegations of Regulatory Misconduct Branch at [OCMedicalDeviceCO@fda.hhs.gov](mailto:OCMedicalDeviceCO@fda.hhs.gov)."

#### Cooperation

OtisMed shall cooperate completely and truthfully in any trial or other proceeding arising out of any civil, criminal or administrative investigation of its current and former officers, agents, employees and customers in connection with matters described in the Information. OtisMed shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with matters described in the Information. OtisMed shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in the Information.

In addition, OtisMed shall promptly furnish to any federal agency, upon its request, all non-privileged documents and records in its possession, custody, or control relating to the conduct that are within the scope of any investigation,

proceeding, or trial, in connection with the matters described in the Information.

Notwithstanding any provision of this agreement, (1) OtisMed is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney or that they act contrary to that advice; (2) OtisMed is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) OtisMed is not required to waive any privilege or claim of work product protection.

#### Other Provisions

OtisMed agrees that it is authorized to enter into this agreement, that it has authorized the undersigned corporate representative, Michael Cartier, to take this action, and that all corporate formalities for such authorization have been observed. By entering this guilty plea, OtisMed hereby waives all objections to the form of the charging document and admits that it is in fact guilty of the offense charged in the Information.

#### Corporate Authorization


OtisMed's corporate acknowledgment of: (a) this agreement; and (b) the corporate resolution authorizing entry into and execution of this agreement, is attached as Exhibit 4. OtisMed has provided to the United States a certified copy of a resolution of the governing body of OtisMed, affirming that it has authority to enter into this agreement and has (1) reviewed this plea agreement and the Information in this case; (2) consulted with legal counsel in this matter; (3) authorized execution of this agreement; (4) authorized OtisMed to plead guilty to the Information; and (5) authorized Michael Cartier to execute this agreement and all other documents necessary to carry out the provisions of this agreement. A copy of this resolution is attached hereto as Exhibit 5.

No Other Promises

This agreement and the Exhibits hereto constitute the plea agreement between OtisMed and the United States and together their terms supersede any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.


Very truly yours,

PAUL J. FISHMAN  
United States Attorney

  
\_\_\_\_\_  
JACOB T. ELBERG  
Chief  
Health Care & Government Fraud Unit  
U.S. Attorney's Office  
District of New Jersey

ROSS S. GOLDSTEIN  
Trial Attorney  
Consumer Protection Branch  
U.S. Department of Justice

APPROVED:

  
\_\_\_\_\_  
THOMAS J. EICHER  
Chief  
Criminal Division  
U.S. Attorney's Office  
District of New Jersey

I am the authorized corporate representative for OtisMed Corporation ("OtisMed"). I have received this letter from Brien T. O'Connor, Esq. and Joshua S. Levy, Esq., who are the attorneys for OtisMed. I have read the letter, and Mr. O'Connor, Mr. Levy and I have discussed it and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. I understand this letter fully. On behalf of and with the express authorization of OtisMed, I hereby accept its terms and conditions and acknowledge that it constitutes the plea agreement between the parties. OtisMed understands that no additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties. OtisMed wants to plead guilty pursuant to this plea agreement.

AGREED AND ACCEPTED:



Michael Cartier

As Authorized Corporate Representative  
for OtisMed Corporation

Date: September 12, 2014

I am counsel for OtisMed Corporation ("OtisMed"). I have discussed with my client this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. Further, I have fully advised the authorized corporate representative, Michael Cartier, of OtisMed's rights regarding this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. My client, OtisMed, understands this plea agreement fully and wants to plead guilty pursuant to it.



BRIEN T. O'CONNOR, Esq.

JOSHUA S. LEVY, Esq.

Date: September 15, 2014



Schedule A

1. The United States and OtisMed agree to stipulate to the following facts:

(a) Between May 2006 and November 2009, OtisMed distributed more than 18,000 OtisKnee devices to surgeons throughout the United States. From May 2006 to October 2008, OtisMed had not sought or received approval or clearance from the Food and Drug Administration (FDA) to market or distribute the OtisKnee in interstate commerce and distributed the OtisKnee, taking the position that the OtisKnee was a Class I device and exempt from FDA premarket approval and clearance requirements.

(b) On October 2, 2008, OtisMed submitted a premarket notification pursuant to 21 U.S.C. § 360(k) (known as a "510(k) notification") seeking FDA clearance to market the OtisKnee. On or about September 2, 2009, the FDA sent OtisMed a notice that its 510(k) submission had been denied. Specifically, the FDA notified OtisMed that the FDA had determined that the OtisKnee was not substantially equivalent to another approved Class I or Class II device, and OtisMed had not demonstrated the OtisKnee to be as safe and effective as other legally marketed devices (the "NSE Letter").

(c) The NSE Letter informed OtisMed that "[a]ny commercial distribution of [the OtisKnee] prior to approval of a [premarket approval application], or the effective date of any order by the Food and Drug Administration re-classifying [the OtisKnee] into Class I or Class II would be a violation of the [Federal Food, Drug, and Cosmetic Act]."

(d) Between September 2, 2009, and September 9, 2009, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed received advice from legal and regulatory counsel confirming that, based on the NSE Letter, it would be unlawful for OtisMed to continue distributing the OtisKnee.

(e) Despite the NSE Letter and against the advice from legal counsel, on or about September 10, 2009, OtisMed's Chief Executive Officer Charlie Chi ordered OtisMed employees to distribute more than 200 OtisKnee devices to surgeons throughout the United States from OtisMed's facility in California. Because these medical devices did not have the required clearance or approval of the FDA, they were adulterated as a matter of law.

(f) OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed took steps to conceal these shipments from the FDA. Among other things, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed kept the shipments secret from OtisMed's Board of Directors and OtisMed's attorneys who were communicating with the FDA. In addition, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed did not inform surgeons at the time of the September 10, 2009, shipments that the FDA had determined that the OtisKnee had not been demonstrated to be safe and effective for its intended use, and that the device could therefore not be lawfully introduced into interstate commerce. OtisMed distributed the devices despite knowledge that surgeons relied on OtisMed's prior representations that the OtisKnee was legally marketed. As such, OtisMed's Chief Executive Officer Charlie Chi and others at OtisMed distributed these OtisKnee devices with the intent to defraud or mislead.

2. In accordance with the above, and pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the parties agree that the following sentence (hereinafter the "Stipulated Sentence") is reasonable, taking into account all of the factors under 18 U.S.C. §§ 3553(a) and 3572:

- (a) OtisMed shall pay a criminal fine in the amount of \$34,400,000;
- (b) OtisMed shall pay forfeiture in the amount of \$5,160,000;
- (c) OtisMed shall pay a special assessment of \$400;
- (d) OtisMed shall not be ordered to pay restitution; and
- (e) OtisMed shall not be subject to a term of probation.

3. The parties further agree that neither party will argue for a sentence that varies from any of the terms of the Stipulated Sentence.

# Exhibit 1

### SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”); the Defense Health Agency, acting on behalf of the TRICARE Program (“DHA”), through its General Counsel (collectively the “United States”); OtisMed Corporation, Stryker Corporation, Howmedica Osteonics Corporation (collectively “Defendants”), and Richard Adrian (“Relator”), (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. OtisMed Corporation (“OtisMed”) is a biotechnology corporation based in Alameda, California. During the time period from January 2006 to September 2009, OtisMed developed, manufactured, and sold “OtisKnee Orthopedic Cutting Guides.” The OtisKnee was intended for use as an aid in positioning orthopedic implants and guiding the marking of osseous tissue before initial cuts during a total knee replacement surgery. In November 2009, Stryker Corporation (“Stryker”) acquired OtisMed and OtisMed now operates as a wholly-owned subsidiary within Stryker’s Orthopaedics Division, Howmedica Osteonics Corporation (“Howmedica”).

B. On October 2, 2009, Richard Adrian filed a *qui tam* action in the United States District Court for the District of New Jersey captioned *United States ex rel. Adrian v. OtisMedCorp. et al.*, Civil No. 09-cv-5083, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”).



C. On such date as may be determined by the Court, OtisMed will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information filed in United States of America v. OtisMed Corp., Criminal Action No. [to be assigned] (District of New Jersey) (the "Criminal Action") that will allege a violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(f)(1)(B), namely, the introduction into interstate commerce, with the intent to defraud or mislead, of an adulterated medical device, the OtisKnee Orthopedic Cutting Guide, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA").

D. Defendants have entered or will be entering into separate settlement agreements, described in Paragraph 1.b. below (hereinafter referred to as the "Medicaid State Settlement Agreements"), with certain states and the District of Columbia in settlement of the Covered Conduct. States with which Defendants execute a Medicaid State Settlement Agreement in the form to which Defendants and the National Association of Medicaid Fraud Control Units ("NAMFCU") have agreed, or in a form otherwise agreed to by Defendants and an individual state, are referred to herein as "Medicaid Participating States."

E. The United States contends that OtisMed submitted or caused to be submitted claims for payment for total knee replacement surgeries that used the OtisKnee to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the FEHBP, 5 U.S.C. §§ 8901-8914; the TRICARE Program, 10 U.S.C. §§ 1071-1110a; and the Medicaid Program ("Medicaid"), 42 U.S.C. §§ 1396- 1396w-5 (collectively, the "Federal Health Care Programs"); between January 2006 and November 2009.

F. The United States contends that it and the Medicaid Participating States have certain civil claims against Defendants, relating to the period from January 2006 through November 2009, arising from the marketing and distribution of the OtisKnee Orthopedic Cutting

Guide, a medical device, without receiving approval or clearance from the FDA for the device. Specifically, in May 2006, OtisMed, through co-promotion activities with Stryker, began commercially distributing the OtisKnee without having received clearance or approval from the FDA for the device. In October 2008, OtisMed submitted a 510(k) application to the FDA, but continued to distribute the device while the 510(k) was under FDA review. On September 2, 2009, the FDA informed OtisMed that it had not demonstrated that the OtisKnee was as safe and effective as legally marketed devices and thus could not be lawfully distributed until FDA approved the device. Even after receiving this letter, OtisMed continued to distribute the OtisKnee.

In addition, the United States also contends that OtisMed encouraged health care providers to submit claims for magnetic resonance imaging (MRIs) that were not reimbursable because they were not performed for diagnostic use, but rather were only performed to provide data for the creation of the OtisKnee.

As a result of the foregoing conduct, the United States contends that Defendants knowingly caused the submission of false and fraudulent claims for procedures using the OtisKnee to Federal Health Care Programs and Defendants obtained proceeds and profits to which they were not entitled, from January 2006 through November 2009.

The conduct described in Paragraph F is referred to herein as the Covered Conduct.

G. This Agreement is made in compromise of disputed claims. Defendants deny the United States' allegations in Paragraph F and the Relator's allegations in the Civil Action, except to the extent admitted in OtisMed's guilty plea. This Settlement Agreement is neither an admission of liability by Defendants, nor a concession by the United States that its claims are not well founded.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendants shall pay to the United States and the Medicaid Participating States, collectively, the sum of \$40,000,000 plus interest at a rate of 2.14% per annum accruing from May 17, 2013 (the "Settlement Amount"), as set forth below:

- a. Defendants shall pay to the United States the amount of \$40,781,532, including accrued interest (the "Federal Settlement Amount"). If the Federal Settlement Amount is not paid by September 22, 2014, Defendants shall pay additional interest at a rate of 2.14% per annum from September 22, 2014, until the date of payment. The Federal Settlement Amount shall be paid pursuant to written instructions to be provided by the Department of Justice, by electronic funds transfer, no later than seven (7) days after (i) the Effective Date of this Agreement; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later.
- b. Defendants shall pay to the Medicaid Participating States the amount of \$376,700, including accrued interest (the "Medicaid State Settlement Amount"). If the Medicaid State Settlement Amount is not paid by September 22, 2014, Defendants shall pay additional interest at a rate of

2.14% per annum from September 22, 2014, until the date of payment.

The Medicaid State Settlement Amount shall be paid pursuant to the terms of the Medicaid State Settlement Agreements or otherwise agreed to by Defendants and the National Association of Medicaid Fraud Control Units.

- c. If OtisMed's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Defendants. If either the United States or Defendants exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Defendants will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the United States within 90 calendar days of rescission, except to the extent such defenses were available on the day on which the Civil Action listed in Preamble Paragraph B, above, was filed.

2. On or about the Effective Date of this Agreement, Defendants and Relator will enter into a separate agreement with respect to the payment by Defendants of Relator's attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).



3. Conditioned upon the United States receiving the Settlement Amount from Defendants and as soon as feasible after receipt, the United States shall pay \$7,013,477 to Relator by electronic funds transfer.

4. Subject to the exceptions in Paragraph 9 (concerning excluded claims) below, and conditioned upon the full payment of the Settlement Amount, the United States releases Defendants from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 2 above and Paragraph 9 below, and conditioned upon Defendants' full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Defendants from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6.
  - a. In compromise and settlement of the rights of OIG HIS to exclude OtisMed pursuant to 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7(a)(3) for the conduct described in Paragraphs C and F, OtisMed agrees to be excluded under these statutory provision from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f), for twenty (20) years. Such exclusion shall have national effect. Federal health care programs shall not pay OtisMed or anyone else for items or services, including administrative and management services, furnished, ordered, or prescribed by OtisMed in any capacity while

OtisMed is excluded. This payment prohibition applies to OtisMed and all other individuals and entities (including, for example, anyone who employs or contracts with OtisMed, and any hospital or other provider where OtisMed provides services). The exclusion applies regardless of who submits the claims or other request for payment.

- b. OtisMed further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for items or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. OtisMed waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court.
- c. OtisMed understands that violations of the conditions of exclusion may subject it to criminal prosecution, the imposition of civil money penalties and assessments, and an additional period of exclusion (see 42 U.S.C. §§ 1320a-7b and 1320a-7a).
- d. Reinstatement to program participation is not automatic. If OtisMed wishes to be reinstated, OtisMed must submit a written request for reinstatement to the OIG HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Such request may be made to OIG HHS no earlier than 120 days prior to the expiration of the period of exclusion reflected in Paragraph 6.a. Reinstatement becomes effective only upon notice of reinstatement by OIG HHS after OIG HHS approval of the

application by OtisMed. Obtaining another license, moving to another state, or obtaining a provider number from a Medicare contractor, a state agency, or a Federal health care program does not reinstate OtisMed's eligibility to participate in these programs.

- e. OtisMed shall not contest, in any manner, the terms or provisions of Paragraph 6 of this Agreement, nor shall OtisMed seek any remedy or relief for any matter, cause of action, or claim arising from implementation of Paragraph 6 of this Agreement. OtisMed expressly waives all procedural rights granted under the OIG HHS's exclusion authority and regulations, section 1128 of the Act, 42 U.S.C. § 1320a- 7, and 42 C.F.R. Part 1001, including, but not limited to any notice, hearing, or appeal with respect to its exclusion.

7. DHA expressly reserves authority to exclude Stryker and Howmedica from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(l)(i)(A), (f)(l)(i)(B), and (f)(l)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below. The exclusion of OtisMed described in Paragraph 6, which includes "all other Federal Health care programs, as defined in 42 U.S.C. 1320A-7B(F)," includes the TRICARE program.

8. OPM expressly reserves all rights to institute, direct or to maintain any administrative action seeking debarment against Stryker and Howmedica and/or their officers, directors, and employees from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment). Nothing in this Paragraph precludes OPM from taking action

against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below. For the purposes of this settlement agreement, the term “Federal health care program” in Paragraph 6 above shall include the FEHBP authorized under 5 U.S.C. Chapter 89. OtisMed expressly waives all procedural rights granted under the U.S. Office of Personnel Management’s authority and regulations, 5 U.S.C § 8902a and 5 C.F.R. Part 890, Subpart I, including, but not limited to any notice, hearing, or appeal with respect to its debarment.

9. Notwithstanding the releases given in Paragraphs 4 and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or



i. Any liability of individuals.

10. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 3, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

11. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Defendants, and its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action. Defendants and its officers, agents, and employees, release Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns from any liability arising from the filing of the Civil Action.

12. Defendants waive and shall not assert any defenses Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

13. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier); TRICARE fiscal intermediary, carrier; and/or contractor, FEHBP carrier or payer; or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare carrier or intermediary; TRICARE fiscal intermediary, carrier, and/or contractor; FEHBP fiscal agent; or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

15. Defendants agree to the following:

- a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendants, its present or former officers, directors, employees, shareholders, and agents in connection with:
  - 1) the matters covered by this Agreement and any related plea agreement;

- 2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- 3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- 4) The negotiation and performance of this Agreement and any plea agreement; and
- 5) the payment Defendants make to the United States pursuant to this Agreement and any payments that Defendants may make to Relator, including costs and attorney's fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendants, and Defendants shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Defendants or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

Defendants further agree that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendants or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Defendants or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendants or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Defendants shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 18 (waiver for beneficiaries paragraph), below.

18. Defendants agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

19. Upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). Such dismissal shall be with prejudice to Relator and the



United States as to the Covered Conduct; and with prejudice to Relator and without prejudice to the United States as to all other claims in the Complaint.

20. Except as set forth in Paragraph 2 above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

21. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

22. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of New Jersey. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

24. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

26. This Agreement is binding on Defendants' successors, transferees, heirs, and assigns.

27. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

28. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 9.16.14

BY: 

CHARLES J. BIRO  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLES GRAYBOW  
Assistant U.S. Attorney  
Office of the United States Attorney  
for the District of New Jersey

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ROBERT K. DECONTI  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the  
Inspector General Office of Inspector  
General  
United States Department of  
Health and Human Services

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

PAUL J. HUTTER  
General Counsel  
TRICARE Management Activity  
United States Department of Defense

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ALAN P. SPIELMAN  
Assistant Director of Federal Employee  
Insurance Operations  
United States Office of Personnel  
Management

THE UNITED STATES OF AMERICA

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLES J. BIRO  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: Sept. 15, 2014

BY: Charles Graybow

CHARLES GRAYBOW  
Assistant U.S. Attorney  
Office of the United States Attorney  
for the District of New Jersey

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ROBERT K. DECONTI  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the  
Inspector General Office of Inspector  
General  
United States Department of  
Health and Human Services

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

PAUL J. HUTTER  
General Counsel  
TRICARE Management Activity  
United States Department of Defense

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ALAN P. SPIELMAN  
Assistant Director of Federal Employee  
Insurance Operations  
United States Office of Personnel  
Management

THE UNITED STATES OF AMERICA

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLES J. BIRO  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLES GRAYBOW  
Assistant U.S. Attorney  
Office of the United States Attorney  
for the District of New Jersey

DATED: 9/15/14

BY: Robert K. DeConti

ROBERT K. DECONTI  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the  
Inspector General Office of Inspector  
General  
United States Department of  
Health and Human Services

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

PAUL J. HUTTER  
General Counsel  
TRICARE Management Activity  
United States Department of Defense

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ALAN P. SPIELMAN  
Assistant Director of Federal Employee  
Insurance Operations  
United States Office of Personnel  
Management

THE UNITED STATES OF AMERICA

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
CHARLES J. BIRO  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

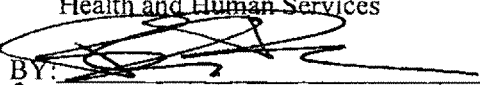
DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
CHARLES GRAYBOW  
Assistant U.S. Attorney  
Office of the United States Attorney  
for the District of New Jersey

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
ROBERT K. DECONTI  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the  
Inspector General Office of Inspector  
General  
United States Department of  
Health and Human Services

DATED: 9/12/2014

BY:  \_\_\_\_\_  
PAUL J. HUTTER  
General Counsel  
TRICARE Management Activity  
United States Department of Defense

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
ALAN P. SPIELMAN  
Assistant Director of Federal Employee  
Insurance Operations  
United States Office of Personnel  
Management



THE UNITED STATES OF AMERICA

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLES J. BIRO  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLES GRAYBOW  
Assistant U.S. Attorney  
Office of the United States Attorney  
for the District of New Jersey

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ROBERT K. DECONTI  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the  
Inspector General Office of Inspector  
General  
United States Department of  
Health and Human Services

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

PAUL J. HUTTER  
General Counsel  
TRICARE Management Activity  
United States Department of Defense

DATED: 9/12/14

BY: Alan P. Spielman

ALAN P. SPIELMAN  
Assistant Director of Federal Employee  
Insurance Operations  
United States Office of Personnel  
Management

OTISMED CORP., STRYKER CORP., HOWMEDICA OSTEONICS - DEFENDANT'S

DATED: September 12, 2014

BY: Michael A. Cartier  
MICHAEL CARTIER  
As Authorized Corporate Representative for  
OtisMed Corp., Stryker Corp., and  
Howmedica Osteonics Corp.

DATED: September 15, 2014

BY: B.T.O'C  
BRIEN T. O'CONNOR  
JOSHUA S. LEVY  
Counsel for OtisMed Corp., Stryker Corp.,  
and Howmedica Osteonics, Corp.

RICHARD ADRIAN - Relator

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
RICHARD ADRIAN

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
JOSEPH M. CALLOW, JR  
KEATING, MUETHING & KLEKAMP PLL  
Counsel for Richard Adrian

OTISMED CORP., STRYKER CORP., HOWMEDICA OSTEONICS - DEFENDANTS

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
MICHAEL CARTIER  
As Authorized Corporate Representative for  
OtisMed Corp., Stryker Corp., and  
Howmedica Osteonics Corp.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
BRIEN T. O'CONNOR  
JOSHUA S. LEVY  
Counsel for OtisMed Corp., Stryker Corp.,  
and Howmedica Osteonics, Corp.

DATED: 9/12/2014 RICHARD ADRIAN - Relator

BY: Richard Adrian  
RICHARD ADRIAN

DATED: 9/14/2014

BY: Joseph M. Callow, Jr.  
JOSEPH M. CALLOW, JR  
KEATING, MUETHING & KLEKAMP PLL  
Counsel for Richard Adrian

# Exhibit 2



**U.S. Department of Justice**

*United States Attorney  
District of New Jersey*

---

*970 Broad Street, 7<sup>th</sup> floor  
Newark, New Jersey 07102*

*973-645-2700*

August 29, 2014

Mr. Brien T. O'Connor  
Mr. Joshua S. Levy  
Ropes & Gray  
One International Place  
Boston, Massachusetts 02110

Re: United States v. OtisMed; Side Letter Agreement with  
Stryker Corporation

Dear Messrs. O'Connor and Levy:

This letter ("Side Letter Agreement" or "Agreement") sets forth the terms of the agreement between your client, Stryker Corporation ("Stryker"), and the United States of America, acting through the United States Attorney for the District of New Jersey and the Consumer Protection Branch of the U.S. Department of Justice (collectively, "the United States"). In exchange for Stryker's full performance of the terms contained within this Side Letter Agreement and the Plea Agreement entered into by OtisMed Corporation (attached hereto as Exhibit A), the United States and Stryker Corporation ("Stryker") hereby agree as follows:

**Charge and Plea Agreement with OtisMed Corporation**

On or about September 17, 2014, the United States will file an Information in the United States District Court for the District of New Jersey charging OtisMed with the introduction into interstate commerce, with the intent to defraud and mislead, of medical devices that were adulterated (pursuant to 21 U.S.C. § 351(f)(1)(B)), in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(2). Stryker Corporation acquired OtisMed Corporation ("OtisMed") on November 10, 2009. Since that date, Stryker Corporation has operated OtisMed as a wholly-owned subsidiary within Stryker's Orthopaedics division. The United States acknowledges that the conduct that forms the basis of the criminal charge occurred prior to Stryker's acquisition of OtisMed and without Stryker's prior knowledge or acquiescence.

Pursuant to the Plea Agreement attached as Exhibit A, entered into between OtisMed and the United States, OtisMed will plead guilty to the Information and agrees to comply with all terms of the Plea Agreement, provided that the district court accepts OtisMed's guilty plea and agrees to enter a judgment of conviction consistent with the agreed-upon disposition pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure.



### **No Criminal Prosecution of Stryker Corporation**

Conditioned upon the performance of terms set forth below in the section entitled "Cooperation by Stryker," the United States hereby agrees to decline prosecution of Stryker or any of its subsidiaries (except for OtisMed as set forth in the Information) for conduct by or attributable to Stryker or any of its subsidiaries that:

- Falls within the scope of the Information to which OtisMed is pleading guilty;
  - Was a subject of the investigation regarding the "Custom Fit Total Knee Replacement with OtisKnee" (hereinafter "OtisKnee") medical devices; or
  - Was otherwise known to the U.S. Attorney for the District of New Jersey and the Consumer Protection Branch of the U.S. Department of Justice prior to December 8, 2014, in connection with any allegations that Stryker may have:
1. Promoted, marketed, and sold the OtisKnee for use in orthopedic surgeries without marketing approval or clearance from the Food and Drug Administration ("FDA");
  2. Conspired with others to introduce or deliver or cause the introduction or delivery into interstate commerce of the OtisKnee while adulterated;
  3. Aided or abetted OtisMed in violating the FDCA with regard to the OtisKnee; or
  4. Carried out any acts that resulted in Stryker's Triathlon Total Knee Replacement System becoming adulterated or misbranded when used, or intended by Stryker to be used, in conjunction with the OtisKnee.

This Side Letter Agreement is not intended to, and does not, affect any criminal liability of any natural person. It is understood and agreed among the parties to this Side Letter

Agreement that the promise of the United States not to prosecute Stryker is contingent upon and subject to OtisMed fulfilling its obligations as set forth in the Plea Agreement.

#### **Who is Bound By Agreement**

This Side Letter Agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys and the Criminal Division, and the Consumer Protection Branch in the Civil Division (United States), except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of Treasury. The non-prosecution provisions of this Side Letter Agreement are binding on the United States, with the exception of any investigations of Stryker, its subsidiaries, affiliates, or parent that are or may be conducted in the future by the Fraud Section of the Criminal Division of the United States Department of Justice regarding possible violation of the Foreign Corrupt Practices Act and related offenses, in connection with the sales and marketing of Stryker's products to foreign customers, which investigations are specifically excluded from the release in this Side Letter Agreement.

#### **Term of Agreement**

This Side Letter Agreement is effective for a period beginning on the date on which the United States District Court

for the District of New Jersey enters a Judgment of Conviction against OtisMed pursuant to the Plea Agreement attached as Exhibit A (the "Effective Date") and shall be binding for a period of three years from the Effective Date.

#### **Notice to Stryker Employees**

Within ten (10) days of the Effective Date of this Side Letter Agreement, Stryker will communicate to all employees of the Knee Business Unit within the Reconstructive Division of the Orthopaedics Group within Howmedica Osteonics or any subsequently named business unit that encompasses knee products within Howmedica Osteonics (the "Knee Business Unit") that OtisMed pleaded guilty to the Information and that Stryker entered into this Side Letter Agreement. Stryker will distribute the OtisMed Information, this Agreement, and the Statement of Facts to all such employees. Within ninety (90) days after OtisMed is sentenced pursuant to the Plea Agreement, Stryker will ensure that OtisMed fulfills its obligations under the Plea Agreement with regard to providing the required Notice to Healthcare Providers as set forth therein.

#### **Compliance Measures**

After the conduct giving rise to the criminal prosecution of OtisMed and prior to entering into this Side Letter Agreement, OtisMed was acquired by Stryker. As the current

owner of OtisMed, Stryker agrees to the following Compliance provisions and obligations.

*Stryker's Compliance Program*

Stryker has in place and will maintain a Compliance Program, which governs all Stryker divisions, including the Knee Business Unit. The Compliance Program consists of

- A Chief compliance Officer;
- A Corporate Compliance Committee;
- Divisional Compliance Officers;
- Divisional Compliance Committees;
- Policies and Procedures governing Stryker employee conduct;
- Education and training programs for Stryker employees regarding applicable laws, policies, and procedures.
- A Compliance Hotline to allow Stryker employees to report conduct or activity they believe may be illegal, improper, or unethical;
- An Ethics Hotline Committee; and
- An anti-retaliation policy.

Stryker agrees to continue to establish and maintain policies and procedures designed to prevent violations of the FDCA regarding the sale, marketing, and promotion of medical devices.

The Stryker Board of Directors will establish compliance oversight responsibilities for its Governance and Nominating Committee (the "Governance Committee"). The Committee will be

appointed annually by the Board of Directors and will consist of at least two directors, each of whom has been affirmatively determined by the Board of Directors to be independent of Stryker. The Governance Committee will report issues to the full Board of Directors as the Governance Committee deems appropriate.

The Governance Committee's oversight responsibilities shall include issues regarding Stryker's compliance with applicable law and regulations, including processes and procedures for management's monitoring of compliance. The Stryker Group President of Global Quality and Operations will report on regulatory affairs and quality assurance issues to the Governance Committee at least annually. An independent expert on the FDCA and FDA regulations will be retained by the Board and will report on trends on regulatory and compliance issues to the Governance Committee at least annually.

*Clinical Trial Data Bank Requirements*

A. Within 180 days of the Effective Date of this Side Letter Agreement, Stryker will conduct an audit of its records regarding any "ongoing" (as that term is defined by 42 U.S.C. § 282(j)) "clinical investigations" (as that term is defined by 21 C.F.R. § 50.3) in which the test article is a device marketed by the Reconstructive Division of the Orthopedics Group of which

Stryker is a "responsible party" (as that term is defined by 42 U.S.C. § 282(j)). With regard to each clinical investigation, Stryker will determine whether there has been compliance with the requirements of Section 282 of Title 42, United States Code. A written report of the results of this audit will be provided to the Government at the addresses below no later than sixty (60) days following the audit's completion. For any clinical investigation in which the audit reveals that there has been less than full compliance, Stryker will achieve compliance within 120 days of the audit's completion.

B. Beginning on December 31, 2014, and continuing on an annual basis for two years, Stryker will include in its annual certifications (as described below) that, to the best of its knowledge, all ongoing clinical investigations studying health outcomes for which Stryker is a "responsible party" (including uncontrolled studies, but excepting small feasibility studies and pediatric postmarket surveillance studies) in which the test article is a medical device (subject to 21 U.S.C. §§ 360(k), 360e, or 360j(m)) and is manufactured, distributed, or marketed by the Reconstructive Division of the Stryker Orthopaedics Group have been registered in the national clinical trial registry data bank in accordance with Section 282 of Title 42, United States Code.



*Device Classification & Market Pathway Review*

Stryker shall conduct a review and audit of all Letters to File for all marketed devices within the Knee Business Unit (including any marketed devices subject to co-promotion by the Knee Business Unit with or on behalf of a non-Stryker entity) from April 9, 2009 to present to assess and evaluate the devices' classification and regulatory status. As part of the review, Stryker will evaluate its systems, processes, policies, and procedures relating to the classification, pathway to market, and regulatory status of these devices, including evaluating any decisions whether or not to file premarket approval applications and/or premarket notifications.

Stryker will report the results of this audit to the United States and the FDA Center for Devices and Radiological Health ("CDRH") no later than sixty (60) days following its completion. However, nothing with regard to this requirement is intended to relieve Stryker of any of its obligations under the FDCA or FDA regulations, including with regard to violative devices.

*Corrective and Preventative Action & Medical Device Reporting Review*

Stryker has in place, and will continue to maintain, policies and procedures within the Knee Business Unit for documenting Corrective and Preventative Actions and for complying with adverse event data reporting to the FDA. In

addition, Stryker will continue to conduct periodic assessments to evaluate and ensure that its adverse event and complaint reporting systems, processes, policies, and procedures are fully implemented and effective in the Knee Business Unit.

*Annual Management Certification*

The President of Stryker's Orthopaedics Group shall conduct a review of Stryker's Compliance Program as it relates to the marketing, promotion, and sale of medical devices within the Knee Business Unit during the preceding year. The first review period shall run from the date of the sentencing of OtisMed through December 31, 2014. Thereafter, the reviews will be conducted on an annual basis for two years.

The Group President, Orthopaedics, shall submit to the United States a signed certification stating that based on his or her review and to the best of his or her knowledge, during the period [insert time period]: (1) Stryker's Compliance Program in the Knee Business Unit continued to include the policies and procedures set forth in this Side Letter Agreement; (2) the Compliance Program was effective in preventing, detecting, and/or remediating, where necessary, violations of the FDCA regarding sales, marketing, and promotion of medical devices within the Knee Business Unit; and (3) the

certifications described with regard to the registration of clinical investigations described above.

The Group President's certification shall summarize the review described above that he or she conducted to provide the required certification. If the Group President is unable to certify that the Compliance Program was effective in preventing, detecting, and/or remediating, where necessary, violations of the FDCA regarding sales, marketing, and promotion of medical devices within the Knee Business Unit, he or she shall explain the steps Stryker is taking to ensure the future effectiveness of the Compliance Program. This explanation will satisfy the certification requirement above with regard to the Compliance Program. If the Group President is unable to provide the certifications associated with the registration of clinical investigations, he or she shall similarly explain the steps Stryker is taking to register the clinical investigations. This explanation will satisfy the certification requirement above with regard to the clinical investigation registry.

*Annual Board of Directors Resolution*

The Board of Directors of Stryker, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of Stryker's Compliance Program as it relates to the marketing, promotion, and sale of medical devices. This

review shall be conducted on an annual basis and shall include, but not be limited to, updates and reports by Stryker's Chief Compliance Officer and other compliance personnel. The review shall evaluate the Compliance Program, including, among other means, by receiving updates about the activities of the Chief Compliance Officer and other company personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with applicable FDCA requirements.

The first review will cover the time period from the date of the sentencing of OtisMed through December 31, 2014. Thereafter the reviews will be conducted on an annual basis for two years. Based on its review, the Board shall submit to the United States a resolution (the "Board Resolution") that summarizes its review and oversight of Stryker's Compliance Program and, at a minimum, includes the following language:

The Board of Directors has made a reasonable inquiry into the content and operations of Stryker's Compliance Program for the time period *[insert time period]*, including the performance of the Chief Compliance Officer and other compliance personnel employed by Stryker. The Board has concluded that, to the best of its knowledge, Stryker has implemented a Compliance Program designed to exercise due diligence to prevent, detect, and remediate misconduct, including violations of the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and is promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law. Stryker's Compliance Program continued to include the policies and procedures set forth in Stryker's Side Letter Agreement with the United States, dated August 29, 2014.

If the Board is unable to provide any part of this statement, it shall include in the resolution an explanation of the reasons why it is unable to provide such a statement about Stryker's Compliance Program.

Stryker shall provide the Certification and Board Resolution to the United States on an annual basis for the term of the Agreement. Stryker shall provide the Certification and Board Resolution to the United States within 60 calendar days following the end of each review period as follows:

Chief, Health Care & Government Fraud Unit  
United States Attorney's Office,  
District of New Jersey  
970 Broad Street, 7<sup>th</sup> Floor  
Newark, NJ 07102

Department of Justice  
Consumer Protection Branch  
P.O. Box 386  
Washington, DC 20044

In addition to providing the results of the audit described in the paragraph entitled "Clinical Trial Data Bank Requirements" to the addresses above, Stryker will also provide the results of the audit to FDA at:

Chief Counsel for Enforcement  
Food & Drug Division, OGC  
White Oak Bldg. 31, Room 4418  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

### **Cooperation by Stryker**

Stryker shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal, or administrative investigation of any current or former officers, agents, employees, or customers of Stryker or OtisMed in connection with the matters described in the paragraph entitled "No Criminal Prosecution of Stryker Corporation" (hereinafter "Relevant Matters"). Stryker shall make all reasonable efforts to facilitate access to, and to encourage the cooperation of, any current or former officers, agents, and employees of Stryker or OtisMed for interviews sought by law enforcement officers or agencies, upon request and reasonable notice in connection with the Relevant Matters. Stryker shall also make all reasonable efforts to encourage current and former officers, agents, and employees of Stryker or OtisMed to testify truthfully and completely before any grand jury, tribunal, or hearing, at which they are requested to do so by any federal agency in connection with the Relevant Matters. In addition, Stryker shall promptly furnish to any federal agency, upon its request, all non-privileged documents and records in its possession, custody, or control relating to the conduct that are within the scope of any investigation, proceeding, or trial, in connection with the Relevant Matters.



Stryker agrees to waive any defenses regarding pre-indictment delay, statutes of limitations, or Speedy Trial Act with respect to any and all criminal charges as set forth above that could have been timely brought or pursued as of the date of this letter, for any part of the term of this Side Letter Agreement during which Stryker fails to fulfill its cooperation obligations, as described herein.

Notwithstanding any provision of this Side Letter Agreement:

- Stryker is not required to request of current or former officer, agents, or employees of Stryker or OtisMed that they forego seeking the advice of an attorney or that they act contrary to any such advice;
- Stryker is not required to take any action against its officers, agents, or employees for acting in accordance with his or her attorney's advice; and
- Stryker is not required to waive any claim of privilege or work product protection.

#### **Remedies for Breach**

Stryker and the United States agree that the only remedy for failure to comply with the obligations set forth in this Side Letter Agreement (other than those dealing with Stryker's cooperation obligations, above) is the imposition of the following monetary penalties in accordance with the following provisions:

- A. A stipulated penalty of \$20,000 per day for each day Stryker: (1) fails to maintain a Compliance Program as set

forth in this Side Letter Agreement, or (2) fails to timely supply the Certification or Board Resolution required in this Side Letter Agreement. With regard to the Certification and Board Resolution, the Stipulated Penalty will begin to accrue on the day after the date the obligation was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.

B. Stryker may submit a timely written request for an extension of time to provide any Certification or Board Resolution required in this Side Letter Agreement. A written request is timely if received by the U.S. Attorney's Office for the District of New Jersey and the U.S. Department of Justice's Consumer Protection Branch at least five business days prior to the date by which the Certification or Board Resolution is due. Timely requests for extension will not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after Stryker fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after Stryker receives the United States'

written denial of such request, or the original due date, whichever is later.

C. Upon the United States' reasonable determination that Stryker has failed to comply with any of the obligations described herein, the United States shall notify Stryker in writing of Stryker's failure to comply and the United States' exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter shall set forth: (i) the provision breached; (ii) the date of the breach; (iii) a description of the breach sufficient to permit Stryker to cure (as described below); and (iv) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter.

D. Within thirty (30) days after receipt of a Demand Letter, or such other period as the United States and Stryker may agree in writing, Stryker shall have the opportunity to cure the breach to the United States' reasonable satisfaction ("Cure Period"). If Stryker cures the breach within the Cure Period, no Stipulated Penalties shall be due. Alternatively, Stryker shall, within thirty (30) days of receipt of such notice, have the opportunity to respond to the United States in writing to explain the nature and circumstances of such breach, including why

Stryker believes whether a breach occurred, whether such breach was material, and whether such breach was knowingly or willfully committed. The United States agrees to consider any such explanation in determining whether to assess a Stipulated Penalty. If Stryker fails to cure the breach during the Cure Period or to provide a satisfactory explanation regarding the breach, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the United States. A joint reasonable determination by the United States Attorney for the District of New Jersey and the Assistant Attorney General for the Civil Division regarding Stryker's failure to comply with any of the obligations described herein will be final and non-appealable. Stryker agrees that the United States District Court for the District of New Jersey shall have jurisdiction over any action to impose such a penalty.

#### **Complete Agreement**


This Side Letter Agreement sets forth all the terms of the agreement between Stryker and the United States. No amendments, modifications, or additions to this Side Letter Agreement shall

be valid unless they are in writing signed by the United States, the attorneys for Stryker, and a representative of Stryker duly authorized by Stryker's Board of Directors.

If the foregoing accurately reflects the agreement entered into between the United States and Stryker, and Stryker's Board of Directors has authorized you to enter into this agreement, please sign below and return the original to AUSA Jacob T. Elberg or DOJ Trial Attorney Ross S. Goldstein.

Very truly yours,

PAUL J. FISHMAN  
United States Attorney




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JACOB T. ELBERG  
Chief  
Health Care & Government Fraud Unit  
U.S. Attorney's Office  
District of New Jersey

ROSS S. GOLDSTEIN  
Trial Attorney  
Consumer Protection Branch  
U.S. Department of Justice

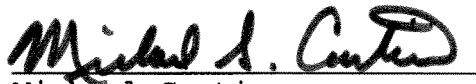
APPROVED:



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THOMAS J. EICHER  
Chief  
Criminal Division  
U.S. Attorney's Office  
District of New Jersey

AGREED AND ACCEPTED:



Michael Cartier

As Authorized Corporate Representative  
for Stryker Corporation

Date: September 12, 2014



BRIEN T. O'CONNOR, Esq.

JOSHUA S. LEVY, Esq.

Counsel for Stryker Corporation

Date: September 15, 2014

# Exhibit 3





U.S. Department of Justice

Criminal Division

*Assistant Attorney General*

*Washington, D.C. 20530*

FEB 03 2014

The Honorable Paul J. Fishman  
United States Attorney  
District of New Jersey  
970 Broad Street, 7th Floor  
Newark, New Jersey 07102

Attention: Jacob T. Elberg  
Assistant United States Attorney

Re: Global Plea Agreement for OtisMed Corporation and Side Letter Agreement for Stryker Corporation

Dear Mr. Fishman:

This is in response to your request for authorization to enter into global agreements with OtisMed Corporation (OtisMed) and Stryker Corporation (Stryker).

I hereby approve the terms of the Plea Agreement with OtisMed, including the provisions on pp. 5-6, through which the United States agrees not to initiate further criminal proceedings against OtisMed for the conduct at issue, with the exceptions and conditions noted within those paragraphs and elsewhere within the Plea Agreement. I also approve the terms of the Side Letter Agreement with Stryker Corporation, including the provisions on pp. 2-3, through which the United States agrees not to initiate criminal proceedings against Stryker for the conduct at issue, with the exceptions and conditions noted within those paragraphs and elsewhere within the Side Letter Agreement.

You are authorized to make these approvals a matter of record in this proceeding.

Sincerely,

Mythili Raman  
Acting Assistant Attorney General

A handwritten signature in dark ink, appearing to read "Paul M. O'Brien", is written over a circular embossed seal. The seal contains the text "DEPARTMENT OF JUSTICE" and "CRIMINAL DIVISION".

PAUL M O'BRIEN  
DEPUTY ASSISTANT ATTORNEY GENERAL  
CRIMINAL DIVISION

# Exhibit 4

ACKNOWLEDGEMENT OF PLEA AGREEMENT

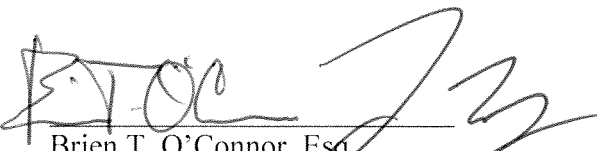
The Board of Directors ("Board") of OtisMed Corporation ("OtisMed") has authorized me to execute this Plea Agreement on behalf of OtisMed, and to take all such action as may be necessary to effectuate this Plea Agreement. The Board has read this Plea Agreement, the related criminal Information, and the related Civil Settlement Agreement, including all attachments, in their entirety, and has discussed them fully in consultation with OtisMed's attorneys. I am further authorized to acknowledge on behalf of OtisMed that these documents fully set forth OtisMed's agreement with the United States, and that no additional promises or representations have been made to OtisMed by any officials of the United States in connection with the disposition of this matter, other than those set forth in these documents.

Dated: September 12, 2014



Michael Cartier  
As Authorized Corporate Representative for  
OtisMed Corporation

Dated: September 15, 2014



Brien T. O'Connor, Esq.  
Joshua S. Levy, Esq.  
Ropes & Gray LLP  
Counsel for OtisMed Corporation

# Exhibit 5

**OTISMED CORPORATION**  
**UNANIMOUS WRITTEN CONSENT OF THE**  
**BOARD OF DIRECTORS**

The undersigned, being all the directors of OtisMed Corporation (the "Company"), a wholly-owned subsidiary of Stryker Corporation, hereby waive all notice of the time, place, or purpose of a meeting and consent to, approve, and adopt the following resolutions without a meeting:

WHEREAS, the United States Attorney's Office for the District of New Jersey and the United States Department of Justice have been conducting an investigation into the Company's conduct relating to the OtisKnee device;

WHEREAS, the Board of Directors has consulted with legal counsel in connection with this matter;

WHEREAS, the Company's legal counsel has been negotiating a resolution of this matter;

WHEREAS, the Company's legal counsel has reported to the Board the terms and conditions of a proposed resolution of this matter;

WHEREAS, the Board of Directors has reviewed, with counsel, the contents of the Information, proposed Plea Agreement, and proposed Civil Settlement Agreement in this matter;

NOW THEREFORE, BE IT:

RESOLVED, that the Company is hereby authorized to enter into the Plea Agreement dated August 29, 2014, between the United States Attorney for the District of New Jersey, the Department of Justice, and OtisMed Corporation (the "Agreement").

FURTHER RESOLVED, that the Company is authorized to plead guilty to the charge specified in the Information.

FURTHER RESOLVED, that Michael Cartier, Deputy General Counsel of Stryker Corporation, or any other Officer of the Company or legal counsel to the Company, are hereby authorized and directed to take all actions and deliver any agreements, certificates, documents, and instruments with respect to or contemplated by the Agreement and matters set forth above, including, without limitation, the payment of all amounts, fees, costs, and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the resolutions contemplated hereby.

This Written Consent may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the undersigned Directors of the Company have executed this consent as of the 10<sup>th</sup> of September, 2014.

A handwritten signature in dark ink, appearing to read 'DF', written over a horizontal line.

David Floyd  
Director, OtisMed Corporation

A handwritten signature in dark ink, appearing to read 'Mark Mania', written over a horizontal line.

Mark Mania  
Director, OtisMed Corporation